

**WASHINGTON D.C.** – Rep. Darrell Issa, the Ranking Member of the Oversight and Government Reform Committee, released [new documents](#) delivered to the Committee by the Food and Drug Administration (FDA) late last night that conclusively reveal that the FDA has issued statements to the media that are inconsistent with key facts related to the investigation and that an FDA official apparently attempted to mislead Congress by omitting key facts about FDA's knowledge of Johnson & Johnson's market withdrawal efforts in 2009.

"Given the information that has come to light during our investigation, it's clear that the FDA was inappropriately defensive and unconstructive when evidence contradicted their previous public statements regarding what they were told by J&J and when," Issa said. "Only after new documents came to light that revealed the FDA was in fact told by Johnson & Johnson about contractors buying Motrin off store shelves did they reverse course and acknowledge what the evidence had been pointing to all along. Now that we've set the record straight on what the FDA knew and when, the conversation now turns to how did this happen and what can be done to ensure that the significant problems at this critically important agency are addressed. When it comes to the safety of the American people, there can be no room for ambiguity and inaction on the part of the entities we rely on to monitor the safety and quality of products like Motrin."

"FDA was unaware of McNeil's 'phantom recall' when it was initiated. Any effort to suggest to the contrary is based on quoting documents selectively and out of context and ignores other evidence as to what occurred," FDA spokeswoman Elaine Gansz Bobo said in an e-mail to the Associated Press last week

In his [prepared opening statement](#) for today's hearing of the House Committee on Oversight and Government Reform, FDA Deputy Commissioner Dr. Sharfstein says: "Because of the

Committee's investigation, we now understand much more about the events...I have not had access to all of the relevant materials gathered in the related criminal investigation...based on what we now know, the "phantom recall" raises important questions for Johnson & Johnson, FDA and Congress...then, in April 2009, the company sent a report to FDA indicating that it was purchasing product from shelves of retailers..."

The following documents provide evidence:

1. San Juan FDA District Director emails (pages 3-8) – these emails show the San Juan FDA District Director Maridalia Torres receiving and forwarding field action reports (FAR) for the Motrin issue filed by McNeil employees for March and April 2009. The March report specifically states that a "third party has been contracted to perform an in store assessment" and the April report states that "product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found."

While copies of the March and April reports were already delivered to the committee by J&J earlier, these FDA emails are proof positive that FDA officials received these key filings that notified the FDA of plans to conduct the soft market withdrawal that FDA would later object to in July.

2. Milind Ganjawala emails and attachments (pages 9-25) – Ganjawala works for the FDA in the Recalls and Shortages Branch of the Office of Compliance. January and February 2010 emails show she is reviewing the complicated and confusing details of the 2009 Motrin recall and is, in particular, focused on the various Motrin FARs filed by McNeil to Maridalia Torres and the San Juan office. In a January 25 email she notes to FDA colleagues that one of the FAR reports filed by McNeil contains a particularly interesting passage. The first sentence of the passage she highlights from the report reads, “In order to confirm that neither affected lots is available at the store level, a third party has been contracted to perform an in store assessment.”

In a February 18 chain with a colleague, Ganjawala is asked to review the accuracy of a paragraph about the Motrin recall that contains the following passage: “Instead of notifying the agency and issuing a recall of the product your firm hired a 3rd party company to buy back the Motrin from the pharmacies and retail locations.” Ganjawala writes back saying, “The firm did notify the FDA via FAR’s. The initial dated 11/26/08, follow up dated 3/23/09, and final dated 4/21/09. According to the document we have the silent recall was ongoing on or around 6/12/09.”

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